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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,302	07/19/2001	Roberto A Macina	DEX-0180	6964
26259	7590	12/02/2004	EXAMINER HOLLERAN, ANNE L	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/806,302	Applicant(s) MACINA, ROBERTO A	
	Examiner Anne Holleran	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 12, 15, 18 and 21 is/are rejected.
- 7) ☒ Claim(s) 13, 14, 16, 17, 19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input checked="" type="checkbox"/> Other: <u>Sequence alignments, 5, 6, 7</u> <i>pages</i></p> |
|---|---|

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/7/2004 has been entered.

Claims 2-10 are canceled and claims 11-21 are added. Claims 1 and 11-21 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

3. The rejection of claims 1, 3, and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of the amendment.

4. The rejection of claims 2 and 4 under 35 U.S.C. 102(e) as being anticipated by Lehrer (Lehrer et al, U.S. Pub. NO.: US 2002/0034739, published March 21, 2002, filing date July 7, 1998) is withdrawn in view of the amendment.

New Grounds of Rejection:

5. Claims 1, 11, 12, 15, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehrer (Lehrer et al, U.S. Pub. NO.: US 2002/0034739 in view of either Ni (U.S. Patent 6,066724; issued May 23, 2000; effective filing date Mar. 21, 1996; cited in the IDS) or Gentz (WO 97/34997; published 25 Sep. 1997; cited in the IDS).

The claimed inventions are drawn to methods for detecting the presence of uterine or ovarian cancer in a patient, comprising measuring levels of a polynucleotide comprising SEQ ID NO: 1 (a polynucleotide encoding ESBPIII having the sequence SEQ ID NO: 2); and comparing the measured levels of the polynucleotide with levels of the polynucleotide in cells, tissues or bodily fluids from a normal human control, wherein an increase in measured levels of the polynucleotide in the patient versus the normal human control is associated with the presence of uterine or ovarian cancer. Because the claims are drawn to methods where the measurements are made in bodily fluids the claimed methods read on detection of metastasis of uterine or ovarian cancer.

Lehrer teaches methods of detection of metastasis of uterine or ovarian cancer comprising the detection of polynucleotides encoding ESBPIII in bodily fluids such as blood. Lehrer fails to teach the specific polynucleotide sequence of SEQ ID NO: 1, but the polynucleotide of Lehrer encodes the same polypeptide as that encoded by SEQ ID NO: 1. Lehrer contemplates detection of genomic variants of polynucleotides encoding the polypeptide encoded by SEQ ID NO: 1. Ni or Gentz teaches a polynucleotide that encodes the polypeptide encoded by SEQ ID NO: 1 and teaches the specific polynucleotide comprising SEQ ID NO: 1 (see enclosed sequence alignments). Therefore, it would have been prima facie obvious to one of ordinary skill in the art

Art Unit: 1642

at the time the invention was made to make a method for the detection of the polynucleotide of Ni or Gentz in the methods of Lehrer to detect uterine or ovarian cancer metastasis in a bodily fluid, because Lehrer teaches methods for detection of metastasis of uterine or ovarian cancer by measurement of the presence of polynucleotides encoding ESBPIII, and because the sequence of SEQ ID NO: 1 was provided by Ni or Gentz prior to the filing date of this application.

Conclusion


Claims 1, 11, 12, 15, 18, and 21 are rejected. Claims 13, 14, 16, 17, 19 and 20 are objected to depending from a rejected claim.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
November 27, 2004


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
11/29/2004

GenCore version 5.1.6
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OM nucleic - nucleic search, using sw model

Run on: November 12, 2004, 22:05:44 ; Search time 58 Seconds
(without alignments)
5833.371 Million cell updates/sec

Title: US-09-806-302a-1
Perfect score: 476
Sequence: 1 acgagctgcacgcagcagct.....cctcaattcattccattca 476

Scoring table: IDENTITY_NUC
Gapop 10.0 , Gapext 1.0

Searched: 824507 seqs, 35539441 residues

Total number of hits satisfying chosen parameters: 1649014

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database : Issued Patents NA: *
1: /cgn2_6/ptodata/1/ina/5A COMB.seq.*
2: /cgn2_6/ptodata/1/ina/5B COMB.seq.*
3: /cgn2_6/ptodata/1/ina/6A COMB.seq.*
4: /cgn2_6/ptodata/1/ina/6B COMB.seq.*
5: /cgn2_6/ptodata/1/ina/PCTUS COMB.seq.*
6: /cgn2_6/ptodata/1/ina/backfiles1.seq.*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match	Length	ID	Description
1	476	100.0	476	3	US-08-821-451A-5
2	476	100.0	476	3	US-09-263-810-5
3	476	100.0	476	3	US-09-583-169-5
4	431.6	90.7	517	3	US-09-673-395A-33
5	223.8	47.0	495	3	US-08-969-387-5
6	223.8	47.0	503	1	US-08-455-896-1
7	223.8	47.0	503	2	US-08-933-149-1
8	223.8	47.0	503	2	US-09-082-343-1
9	223.8	47.0	503	3	US-09-082-253-1
10	223.8	47.0	503	4	US-09-162-622-1
11	223.8	47.0	503	4	US-09-509-015-1
12	223.8	47.0	503	5	PCT-US96-08235-1
13	223.8	47.0	535	3	US-09-215-818-1
14	223.8	47.0	535	4	US-09-457-602A-1
15	201.2	42.3	403	1	US-08-455-896-5
16	201.2	42.3	403	2	US-08-933-149-5
17	201.2	42.3	403	2	US-09-082-343-5
18	201.2	42.3	403	3	US-09-082-253-5
19	201.2	42.3	403	4	US-09-162-622-5
20	201.2	42.3	403	4	US-09-509-015-5
21	201.2	42.3	403	5	PCT-US96-08235-5
22	153.4	32.2	279	4	US-09-162-622-15
23	153.4	32.2	1233	4	US-09-620-405B-492
24	153.4	32.2	1233	4	US-09-834-759-492
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28	153.4	32.2	3288	4	US-09-834-759-490
C 29	140.2	29.5	356	4	US-09-389-681-217
C 30	140.2	29.5	356	4	US-09-620-405B-217
C 31	140.2	29.5	356	4	US-09-339-338-217
C 32	140.2	29.5	356	4	US-09-433-826B-217
C 33	140.2	29.5	356	4	US-09-604-287A-217
C 34	140.2	29.5	356	4	US-09-834-759-217
C	140.2	29.5	356	4	US-09-590-751A-217
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36	122.4	25.7	511	4	US-09-620-405B-182
37	122.4	25.7	511	4	US-09-339-338-182
38	122.4	25.7	511	4	US-09-433-826B-182
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41	122.4	25.7	511	4	US-09-590-751A-182
42	122.4	25.7	511	4	US-08-455-896-6
43	57.2	12.0	206	1	US-08-933-149-6
44	57.2	12.0	206	2	US-09-082-343-6
45	57.2	12.0	206	2	US-09-082-343-6

ALIGNMENTS

RESULT 1
US-08-821-451A-5
; Sequence 5, Application US/08821451A
; Patent No. 6066724
; GENERAL INFORMATION:
; APPLICANT: Jian Ni, Guo-Liang Yu and Reiner Gentz
; TITLE OF INVENTION: Human Endometrial Specific Steroid-
; TITLE OF INVENTION: Binding Factor I, II and III
; NUMBER OF SEQUENCES: 27
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: CARELLA, BYRNE, BAIN, GILFILLAN,
; ADDRESSEE: CECCHI, STEWART & OLSTEIN
; STREET: 6 BECKER FARM ROAD
; CITY: ROSELAND
; STATE: NEW JERSEY
; COUNTRY: USA
; ZIP: 07068
; COMPUTER READABLE FORM:
; MEDIUM TYPE: 3.5 INCH DISKETTE
; COMPUTER: IBM PS/2
; OPERATING SYSTEM: MS-DOS
; SOFTWARE: WORD PERFECT 5.1
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: 60/014,724
; FILING DATE: March 21, 1996
; ATTORNEY/AGENT INFORMATION:
; NAME: MULLINS, J.G.
; REGISTRATION NUMBER: 33,073
; REFERENCE/DOCKET NUMBER: 325800-521 (PF257)
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: 201-994-1700
; TELEFAX: 201-994-1744
; INFORMATION FOR SEQ ID NO: 5:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 476 BASE PAIRS
; TYPE: NUCLEIC ACID
; STRANDEDNESS: SINGLE
; TOPOLOGY: LINEAR
; MOLECULE TYPE: CDNA
US-08-821-451A-5

Query Match 100.0%; Score 476; DB 3; Length 476;
Best Local Similarity 100.0%; Pred. No. 4.6e-145;
Matches 476; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
QY 1 AGGAGCTGCCAGGACGACTGACACAGACAGCCGCTCGCCAGCTGCTGATG 60

UG-09-806

APPLICANT: Gentz, Reiner
 TITLE OF INVENTION: HUMAN ENDOMETRIAL SPECIFIC
 NUMBER OF SEQUENCES: 27
 CORRESPONDENCE ADDRESS:
 ADDRESSEE: CARELLA, BYRNE BAIN, GILFILLAN, CECCHI,
 ADDRESS: STEWART & OLSTEIN
 STREET: 6 BECKER FARM ROAD
 CITY: ROSELAND
 STATE: NEW JERSEY
 COUNTRY: USA
 ZIP: 07068-1739
 COMPUTER READABLE FORM:
 MEDIUM TYPE: Floppy disk
 COMPUTER: IBM PC compatible
 OPERATING SYSTEM: PC-DOS/MS-DOS
 SOFTWARE: Patentin Release #1.0, Version #1.30
 CURRENT APPLICATION DATA:
 APPLICATION NUMBER: PCT/US96/03857

CLASSIFICATION:
ATTORNEY/AGENT INFORMATION:
NAME: Ferraro, Gregory D
REGISTRATION NUMBER: 36,134
REFERENCE/DOCKET NUMBER: 325800-520
TELECOMMUNICATION INFORMATION:
TELEPHONE: 201-994-1700

TELEFAX: 201-994-1744
INFORMATION FOR SEQ ID NO: 5:
SEQUENCE CHARACTERISTICS:
LENGTH: 476 base pairs
TYPE: nucleic acid
STRANDEDNESS: single
TOPOLOGY: linear
MOLECULE TYPE: DNA (genomic)

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FEATURE:
NAME/KEY: CDS
LOCATION: 46..330
FEATURE:
NAME/KEY: sig_pept
LOCATION: 46..108
FEATURE:
NAME/KEY: mat_pept
LOCATION: 109..330

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Query Match	100.0%;	Score 476;	DB 1;	Length 476;
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Db	1	ACGAGCTGCCACGACGACTGAACACAGACAGACGAGCGCCCTCGCCATGAAGCTGCTGATG	60	
Qy	61	GTCTCTATGTCGTGGGGCCCTCCCTCTGCACTGCTATGCAATTCGCTGCTGCAAACTCCTG	120	
Db	61	GTCTCTATGTCGTGGGGCCCTCCCTCTGCACTGCTATGCAATTCGCTGCTGCAAACTCCTG	120	
Qy	121	GAGGACATGTTGAAAGACCATCAATTCGACATATCTATACCTGAATCAAAAGAGCTT	180	
Db	121	GAGGACATGTTGAAAGACCATCAATTCGACATATCTATACCTGAATCAAAAGAGCTT	180	
Qy	181	CTTCAAGAGTTTCATAGCAGCTGATGCCCTGCAGAGCTATGGGAAATTCGAAGCAGTGT	240	
Db	181	CTTCAAGAGTTTCATAGCAGCTGATGCCCTGCAGAGCTATGGGAAATTCGAAGCAGTGT	240	
Qy	241	TTCTCTCAACACAGTTCATAGAACTCTGAAAACTTTGGACTGATGATGCATACAGTGTAC	300	
Db	241	TTCTCTCAACACAGTTCATAGAACTCTGAAAACTTTGGACTGATGATGCATACAGTGTAC	300	
Qy	301	GACAGCATTTGGTGTAAATATGAAGAGTAATTAACCTTATCCGACAGCGCTTTGGCTCAGAGG	360	
Db	301	GACAGCATTTGGTGTAAATATGAAGAGTAATTAACCTTATCCGACAGCGCTTTGGCTCAGAGG	360	

RESULT 2

PCT-US99-22753-1
; Sequence 1, Application PC/TUS9922753

; GENERAL INFORMATION:
; APPLICANT: Macina, Roberto A.

; APPLICANT: DIADEXUS LLC
 ; TITLE OF INVENTION: A Novel Method of Diagnosing, Monitoring, Staging,
 ; TITLE OF INVENTION: Imaging and Treating Gynecologic Cancers

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; FILE REFERENCE: DEX-0045
; CURRENT APPLICATION NUMBER: PCT/US99/22753

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; CURRENT FILING DATE: 1999-09-30
 ; EARLIER APPLICATION NUMBER: 60/102,743

; EARLIER FILING DATE: 1998-10-02
; NUMBER OF SEQ ID NOS: 2

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; SOFTWARE: Pat
; SEQ ID NO 1

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; LENGTH: 476
; TYPE: DNA

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; ORGANISM: Homo sapiens
PCT-US99-22753-1

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Query Match      100.0%; Score 476; DB 1; Length 476;
Best Local Similarity 100.0%; Pred. No. 1.9e-130;
Matches 476; Conservative 0; Mismatches 0; Indels
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	DB		
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	QY	GTCTCTATGCTGGCGGCGCTCCTCCTGCACATGCTATGCAGATTCTGGCTGCAAACTCTCTG	120
	DB		
61	DB	GTCTCTATGCTGGCGGCGCTCCTCCTGCACATGCTATGCAGATTCTGGCTGCAAACTCTCTG	120
	QY		
121	QY	GAGGACATGGTTGAAAGAGACCATCAATTCCGACATATCTATCCTCAATACAAAGAGCTT	180
	DB		
121	DB	GAGGACATGGTTGAAAGAGACCATCAATTCCGACATATCTATCCTCAATACAAAGAGCTT	180
	QY	CTTCAAGAGTTCTATGACACAGTGATCGCGCTGCAGAGGCTATGGGAAAATTCAAGCAGTGT	240
	DB		
181	DB	CTTCAAGAGTTCTATGACACAGTGATCGCGCTGCAGAGGCTATGGGAAAATTCAAGCAGTGT	240
	QY	TTCTCTCAACCACTCACATAGAACTCTGAAAACTTTTGGACTGATGATCATACAGTGATAC	300
	DB		
241	DB	TTCTCTCAACCACTCACATAGAACTCTGAAAACTTTTGGACTGATGATCATACAGTGATAC	300
	QY	GACAGCAATTTGGTGTAAATATGACAGAGTAATTAATCTTTACCCAGGCGTTTGGCTCAGAGG	360
	DB		
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	QY	GCTTTTATGTGGAACTGCTAGACAACTGTTGAAACCTCAATTCAATCCATTTCA	476
	DB		
421	DB	GCTTTTATGTGGAACTGCTAGACAACTGTTGAAACCTCAATTCAATCCATTTCA	476

t. 220